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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/522,716	03/10/2000	Edward P. Cohen	07411.0005.NPUS00	6035

7590 11/17/2004

ATT: IP PROSECUTION
HOWREY, SIMON, ARNOLD & WHITE, LLP
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WASHINGTON, DC 20004-2402

EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/522,716	COHEN, EDWARD P.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26 and 41-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26 and 41-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: Cohen EP
Priority Date: 31 January 1997

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/26/2004 has been entered.
2. Accordingly, claims 1-25, and 27-40 are canceled without prejudice or disclaimer, and claim 54 is newly added.
3. Claims 26, and 41-54 are pending and examined on the merits.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 102

5. The rejection of claims 26,41,42, and 44-45 under 35 USC § 102(b) as being anticipated by Eisenbach *et al* (EP 0569 678 A2) is maintained for the reasons of record. Applicant argues that Eisenbach *et al* do not fulfill the limitation of "total Genomic DNA isolated from the tumor cells of said animal. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. As previously stated (see action mailed 4/11/2003), given its broadest

reasonable interpretation and based on the disclosure of the specification (wherein it is disclosed that the term antigen presenting cell is not limited to professional or constitutive APCs – see pages 18-19), the tumor cells taught by Eisenbach *et al* are considered antigen presenting cells and would inherently comprise “total genomic DNA” from a tumor cell. Because the transfection of genomic DNA into the antigen presenting cell is a process of making the product (i.e. product-by-process, which is not given any patentable weight unless the process by which the product is made creates a structurally different product) and because the method of Eisenbach *et al* appears to use the same product, in the absence of evidence to the contrary, the methods would produce the same effects and is thus anticipated.

In addition, applicant argues that the teachings of Eisenbach *et al* differ from the instant invention in that the MHC genes are cloned and transfected, while that of the instant invention involves the transfection of uncloned total genomic DNA. Applicant concludes that because Eisenbach *et al* do not teach transfection with total genomic DNA, that not all the limitations of the claims have been met in accordance with the standards of the law. Applicant’s arguments have been carefully considered but are not deemed persuasive to overcome the rejection because the claims do not specifically limit the means by which the MHC genes are expressed. Furthermore, nowhere in the claim does it specifically recite that the total genomic DNA is the source of the MHC genes.

Additionally, Applicant argues that the limitation of “sheared total genomic DNA” has not been met by Eisenbach *et al*, in response, it is noted that this claim is newly

added and has not rejection under 35 USC 102(b) as being anticipated by Eisenbach *et al.*

Therefore, the rejection of claims under 35 USC 102(b) is maintained for the reasons of record.

Claim Rejections Maintained - 35 USC § 102

6. The rejection of claims 26,41,42, and 44-45 under 35 USC § 102(e) as being anticipated by Eisenbach *et al* (US Patent 5,750,102) is maintained for the reasons of record. Applicant's arguments are substantially similar to those argued for the 102(b) rejection, *supra*. Applicant's arguments are not deemed persuasive to overcome the rejection of record. See above (paragraph 5) for response to arguments. Therefore, the rejection of claims under 35 USC 102(e) is maintained for the reasons of record.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

7. The rejection of claims 47-53 under 35 USC § 112, 1st paragraph as lacking an enabling disclosure is maintained for the reasons of record. Applicant argues that the claims are not drawn to tumor prevention but rather "preventing of tumor recurrence." Applicant supports their argument by reciting the definition of "recurrence" (see exhibit A). Specifically, applicant states that one of skill would understand that the claims are drawn to a method of inducing partial immunity to a tumor in those patients that "had a tumor in the past" (see page 7, 3rd paragraph). Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The instant specification provides insufficient guidance and objective evidence to predictably enable one of skill in the art to use the invention as claimed. First, the specification teaches (page 36, 2nd full paragraph) that "preventing a tumor means the occurrence of the tumor is prevented". However, the specification has only taught means of treating or inhibiting tumor growth by generation of an immune response or a partial immune response to the tumor (see response page 7, 3rd paragraph). The generation of a partial response to a tumor does not equate to "prevention" as defined in the specification because some tumor cells will escape immune protection if a partial response is generated. Second, the claims can be broadly interpreted as being drawn to a method of "preventing" a tumor in an individual because the claims do not require that the recurrence be of the same tumor type that had occurred in the past. For example, if an individual had breast cancer and was treated effectively with the method of the instant invention for breast cancer the individual can develop ovarian cancer, thus not preventing the recurrence of a tumor. Those of skill in the art of oncology recognize that the state of the art of cancer prevention is relatively unpredictable, the applicant has not provided sufficient evidence that the method of prevention claimed is capable of preventing in view of the unpredictable nature of preventing cancer. Thus the guidance provided in the specification is not sufficient for one of skill in the art to practice the invention within the full scope of the claims. Applicant supports the method of prevention by pointing to the examples in the specification specifically drawn to "preventing", however, as previously stated, the method does not provide sufficient guidance in terms of prevention because the example forces the model to fight the

same type of cancer and does not address question of tumor cells that escape the immune system.

Thus, absent evidence to the contrary, the method is only enabled for treating an individual that *has* a tumor comprising the administration of the antigen presenting cell. Therefore, the rejection of the claims under 35 USC 112, 1st paragraph is maintained for the reasons of record.

NEW ARGUMENTS

Claim Rejections - 35 USC § 112, 1st paragraph

8. Claims 26,41-46, and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION. The claims have been amended to recite "total genomic DNA" as a limitation, however, the addition of the term "total" does not find support in the specification as filed. The applicant points to pages 30-32 for support of the term, however upon review of the specification no support for the term "total" is found. The broadest reasonable interpretation of the term genomic DNA includes a single gene with all its introns and exons. The specification at pages 30-32 only provides support for the broad genus of the term "genomic DNA" and no contemplation of the species "total

genomic DNA” has not been disclosed. Applicant is invited to specifically point out and disclose support for this term.

Conclusion

9. No claim is allowed.
10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Furthermore, this is a continuation examination of applicant's earlier Application No. 09/522716. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
November 3, 2004


GARY NICKOL
PRIMARY EXAMINER